

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): RAYMOND R. RACKLEY et al.	Examiner: THANH, Loan H.
Appln. No.: 10/084,240	Group Art Unit: 1615
Filing Date: February 27, 2002	Docket No. 54459-237216
Title: BULKING AGENT NEEDLE APPARATUS AND METHOD OF USING THE NEEDLE APPARATUS	

I CERTIFY THAT THIS CORRESPONDENCE IS BEING FACSIMILE TRANSMITTED TO THE U.S. PATENT AND TRADEMARK OFFICE (FAX NO. (703) 372-9991) ON AUGUST 2004. January 18, 2005.

Kristine Stefano
Kristine Stefano

DECLARATION OF DEAN A. KLEIN UNDER 37 C.F.R. 1.131

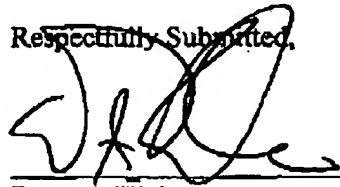
I, Dean A. Klein, declare and state the following:

1. I am an employee of Carbon Medical Technologies, Inc, the assignee of U.S. Patent Application No. 10/084,240 ("the '240 Application"). My current job title is President and Chief Executive Officer of Carbon Medical Technologies.
2. I am a co-inventor of the subject matter disclosed in the '240 Application and I am familiar with the specification and claims of this application.
3. Raymond R. Rackley, Kristina M. Wittchow and I jointly conceived and reduced to practice the invention reported and claimed in the '240 Application prior to June 14, 2001. Attachment 1 is a copy of the Invention Disclosure related to the subject matter described in the '240 Application which I prepared, and is kept as part of our records, prior to June 14, 2001.

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4. I also declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of any patent issued from U.S. Patent Application No. 10/084,240.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read 'D. Klein', written over a horizontal line.

Dean A. Klein

Dated: January 14, 2005

M2:20084990.01

DISCLOSURE FORM

1. ***Specifically describe your invention below. Please use as much detail as possible, explaining how it is different from prior devices or methods for accomplishing the same thing, and how it works to accomplish its desired function. Attach any drawings and/or photographs you have and any other potentially relevant documents.***

This idea relates to an apparatus and method for injecting substances such as a bulking agent to treat stress urinary incontinence, into the soft-tissue plane between the urethra and muscle/proximal urethral submucosa.

The apparatus is a hypodermic needle, with about a 15 degree bend about 3/4" from the tip, and a shield, about 1 1/2" from the tip (3/4" from the bend) that limits the penetration of the needle to about 1 1/2". The total needle length from hub to tip can be any length ≥ 1.5 ", but practically is under 5". The needle tip can have any one of a number of configurations, with the preferred being one that does not core the tissue.

The method of using the needle apparatus is:

- Using standard procedure, prepare the patient for cystoscopy; prepare and prime a needle (needle apparatus described in this disclosure);
- Insert a cystoscope into the urethra to the bladder neck (smaller sheath sizes are preferred);
- Locate the periurethral sinus, an anatomical landmark, located at the lateral border of the medial lip, usually within 1 cm of the lumen. Both the 3 O'clock and 9 O'clock positions along this landmark are potential entry points for the periurethral injection needle (apparatus).
- Penetrate tissue and continue to advance the needle until the needle seems to "pop" or penetrate past the external sphincter. The 15-degree angle of the needle (apparatus) guides it in an arc to the submucosal lining between the urethra and muscle plane. Continue to slowly advance the periurethral injection needle while utilizing the image of the cystoscope to guide the placement.
- To verify placement of the needle (apparatus) utilizing the cystoscopic image, gently wiggle the needle (apparatus) while visualizing the movement through the cystoscope to confirm placement within the submucosa tissue. Only the local area at the needle tip will wiggle if the needle is in the submucosal tissue. If the entire urethra moves, the needle may be in muscle. If this occurs, pull the needle back slightly to reposition it superficially. The shield will be close to the periurethral tissue.
- A syringe containing an injectable solution, typically a bulking agent, is then attached to the needle and injected into the submucosa tissue.

This apparatus is an improvement over the bent needle of Dave Gordon because the bend is shallower reducing the likelihood the needle will kink, allows for a more

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direct placement of the needle tip at the preferred injection site, and works with both large and small diameter needles.

It is an improvement over both Dave Gordon's and Raymond Rackley's needles because it has a penetration shield to prevent the needle tip from penetrating too far, potentially perforating the bladder.

3. ***Attach to this form any brochures or other documents of which you are aware illustrating devices or methods currently in use for accomplishing the same goal as does your invention.***

Bard video "Periurethral Injection Technique Revisited with Dr. Dave Gordon"
Video tape "The Urologic Institute presents Raymond R. Rackley, M.D. Co-head of the section for Voiding Dysfunction and Female Urology"

3. ***When was the first written description of the invention made?***

Dr. RR Rackley visit to CMT without the penetration shield
penetration shield added

4. ***When was the first drawing of the invention completed?***

5. ***If the invention has already been used, indicate the date of first use.***

Bent needle used by Dr. Dave Gordon (30-45° at the hub) & Raymond R Rackley (15° 3/4" from the tip) but not with shield – both uses prior to

6. ***Has the invention ever been offered for sale? If so, when?***

No

7. ***Has the invention ever been reduced to an operable prototype? If so, when?***

Bent needle w/o shield by Dave Gordon & Raymond R Rackley prior to

8. ***What features of the invention do you feel are unique?***

Bend angle; bend location; penetration shield

9. ***Do you know of anyone else who, prior to the time you invented your device, conceived, built, or used the invention? If so, who, when and where?***

See # 7: Dave Gordon, Raymond Rackley at Cleveland Clinic, Cleveland OH, prior to :

10. To your knowledge, has the invention ever been described in a printed publication such as a magazine or technical journal? If so, where and when?

Unknown

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11. Do you feel that anyone other than yourself could be considered an inventor of the invention? If so, who?

Raymond R Rackley, Dea 1 Klein

Date: _____

Signature: _____

for Carbon Medical Technologies
1290 Hammond Road
St. Paul, Minnesota 55110

Date: _____

Witness: _____

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